NOV 0 6 2001

K013496

510(k) SUMMARY

A. Submitted By:

ADAC Laboratories
540 Alder Dr.
Milpitas, CA 95035

Contact: David Kolesar
Tel: (408) 468-3455
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B.

Device Trade Name:	SKYLight Imaging System
Common Name:	Gamma Camera Systems
Classification Name:	Emission Computed Tomography System
Device Class:	21 CFR 892.1200, Class II
Product Code:	90 KPS

C. Date prepared: September 28, 2001

D. Predicate Device: SKYLight Imaging System (K000908)

E. Intended Use:

The SKYLight Imaging System is intended to produce images depicting the anatomical distributions of single photon and positron emitting radioisotopes within the human body for interpretation by medical personnel.

F. Device Description:

The modified SKYLight Imaging System offers all the features of the existing SKYLight Imaging System (K000908) while adding an optional feature that provides the used option or ability to acquire a single head acquisition studies on two separate but simultaneous planar patients. The SKYLight is designed to provide extended imaging functionality relative to a ring style gantry. The SKYLight was designed for single or dual detector nuclear imaging accommodating a broad range of emission computed tomography (ECT) studies. The device includes a gantry frame, two detector arms (with detectors), a collimator storage structure with an acquisition computer unit, a patient imaging table, and a remote hand controller. The modified SKYLight is capable of accommodating two separate patient tables. The gantry is "open" so that a high degree of imaging flexibility is available to image patients sitting, standing or lying down, with or without the included patient imaging table. The patient imaging tables are mechanized to allow for patient loading access and then raised to an imaging height. The tables do not move during imaging since the gantry is flexible enough to perform all required motions for non-circular orbits. The imaging pallet includes removable arm, leg, breast, and headrest supports for patient positioning during studies that require support.

SKYLight is an 'open frame' imaging system, the 'open frame' consisting of an overhead rectangular structure that is supported by 4 (or more) columns that are bolted to the imaging room floor. A detector arm support structure is mounted onto the open frame which allows for the detector arm support structure (and both detector arms) to move in the longitudinal motion (X-axis). Arms that can telescope up and down (Z-axis) support the detectors. These detector arms are supported by a structure that allows for each detector

arm to move toward or away from each other (Y-axis). Each detector has the ability to rotate and acquire images independently

The combination of these four motions (Z, Y, X, and detector rotate), permit the detectors to perform all standard non-circular and circular ECT studies in both the 90-degree and 180-degree relative position. The SkyLight uses the EPIC HP+ detectors. The detectors use standard EPIC collimators, or MCD shields, which may be exchanged using an automatic exchange unit..

The modified SKYLight acquisition computer uses the same acquisition software (subsystem) as existing SKYLight to acquire ECT imaging studies and interfaces with a Pegasys computer system (workstation). The acquisition CPU is used to install the camera software and to archive and restore acquisition parameters and correction tables. The acquisition software is used to complete pre-programmed gantry motions for setup of imaging studies and exchange of collimators; to perform quality assurance tests on the SKYLight system; and to program image parameters and gantry for clinical studies.

When using either a single detector or dual detectors placed in a relative 90-degree or relative 180-degree positions (as study appropriate), SKYLight can be used to perform static, dynamic, gated, total body, circular-orbit and non-circular orbit SPECT studies, coincidence studies, gated SPECT (circular and non-circular) studies, computer-programmed protocol strings, and reference scans (dual detectors only). SPECT and total body acquisitions are routinely acquired with two detectors. There are some planar procedures such as bone statics and lung scan also use two detectors. There are many additional nuclear medicine procedures that only use one detector at a time. These single detector procedures are typically renal, gastric emptying, hepatobiliary, flow studies, GI bleed, thyroid, and delayed static views. This acquisition sub-system interfaces with a Pegasys computer system for entry into the database. The Pegasys workstation also includes software used for image processing, database utilities, and archiving utilities.

G. Technological Comparison:

The modified SKYLight Imaging System and existing SKYLight Imaging System have identical intended use and indications for use. The modified SKYLight and the existing SKYLight are technologically identical. They share the identical mechanical and electrical components. No changes or modifications have been made to the mechanical or electrical components. All the features provided on the existing SKYLight are provided on the modified SKYLight. The only change has been to the acquisition software which provides the modified SKYLight Imaging System an optional feature that allows the user the to acquire a single head acquisition on two separate but simultaneous planar patients.

H. Conclusion

The modified SKYLight Imaging System is substantially equivalent to the predicate device SKYLight based upon identical indications for use, technological comparison and overall system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 6 2001

ADAC Laboratories
% Michael Kwan, Ph.D.
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K013496
Trade/Device Name: SKYLight Imaging System
Gamma Camera System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: October 19, 2001
Received: October 22, 2001

Dear Dr. Kwan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

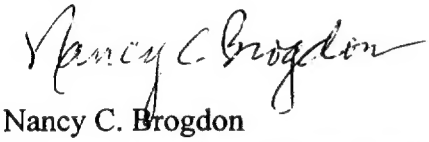
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

NOV 0 6 2001

INDICATIONS FOR USE STATEMENT

510 (k) NUMBER (IF KNOWN): K013496

DEVICE NAME: SKYLight Imaging System

SPONSOR NAME: ADAC Laboratories

INDICATIONS FOR USE:

The SKYLight Imaging System is intended to produce images depicting the anatomical distribution of single photon and positron emitting radioisotopes within the body for interpretation by medical personnel.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David G. Seyson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013496